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PALMER & DODGE, LLP
KATHLEEN M. WILLIAMS
111 HUNTINGTON AVENUE
BOSTON, MA 02199

EXAMINER	
AEDER, SEAN E	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/667,166	SEGAL ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-77* is/are pending in the application.

4a) Of the above claim(s) *42-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41 and 73-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The Amendments and Remarks filed 9/21/07 in response to the Office Action of 3/21/07 are acknowledged and have been entered.

Claims 1-77 are pending.

Claims 42-72 have been withdrawn.

Claims 1, 5, 7, 12, 19, 32, and 76 have been amended by Applicant.

Claims 1-41 and 73-77 are currently under examination.

The following Office Action contains NEW GROUNDS of rejections necessitated by new considerations.

Objections Withdrawn

The objection to the specification is withdrawn.

Rejections Withdrawn

The rejections under 35 U.S.C. 112 second paragraph, are withdrawn.

The rejection under 35 U.S.C. 112, first paragraph, is withdrawn.

The rejections under 35 U.S.C. 102(b) are withdrawn.

The rejection under 35 U.S.C. 102(a) is withdrawn.

The rejections under 35 U.S.C. 103(a) are withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejections of claim 1-41 and 73-77 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over (1) claims 1-4, 7-42, and 74 of copending Applicant No. **10/645000**, (2) claims 16-29 of copending Application No. **10/224661**, (3) claims 1-3, 5, 6, and 9-13 of copending Application No. **10/666833**, (4) claims 1-22, 24, 25, 27-35, 67, and 68 of copending Application No. **10/666871**, (5) claims 1-3, 5, 6, and 9-11 of copending Application No. **10/666886**, (6) claims 1-22, 24, 25, 27-35, 67, and 68 of copending Application No. **10/666898**, and (7) claims 1-28, 30, 31, 33-41, and 73-77 of copending Application No. **10/666834**, are maintained for the reasons stated in the Office Action of 3/21/07.

In the Reply of 9/21/07, Applicant indicates that terminal disclaimers may be filed to obviate these rejections.

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 11, 21, 22, 24-30, 32, 34-35, 37-41, and 75-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoo (US Patent 5,891,432; 4/6/99).

Claim 1 encompasses compositions comprising an antigen bearing target and a fusion polypeptide comprising (1) a first amino acid sequence which can bind sialic acid and (2) a second amino acid sequence that comprises a ligand for a cytokine receptor. Claim 2 is drawn to the composition of claim 1, wherein said antigen bearing target is a cell. Claim 3 is drawn to the composition of claim 2, wherein said cell is a tumor cell. Claim 4 is drawn to the composition of claim 3, wherein said tumor cell is a malignant tumor cell. Claim 5 encompasses compositions of claim 3, wherein said tumor cell is derived from a melanoma. Claim 6 is drawn to the composition of claim 2, wherein said fusion polypeptide is exogenous to said cell. Claim 7 is drawn to the composition of claim 2, wherein said fusion polypeptide is expressed by said cell and is encoded by a nucleic acid comprised by the cell. Claim 8 is drawn to the composition of claim 1, wherein said first amino acid sequence is N-terminal to said second amino acid sequence. Claim 9 is drawn to the composition of claim 1, wherein said first amino acid sequence is C-terminal to said second amino acid sequence. Claim 11 is drawn to the

composition of claim 1, wherein said first amino acid sequence comprises a carbohydrate-binding domain of a naturally occurring lectin. Claim 21 is drawn to the composition of claim 1, wherein the ligand of the second amino acid sequence is a ligand for a mammalian cell surface polypeptide. Claim 22 is drawn to the composition of claim 21, wherein said ligand for a cell surface polypeptide is a ligand for a mouse cell surface polypeptide. Claim 24 is drawn to the composition of claim 1, wherein the ligand of the second amino acid sequence is a ligand for a cell surface polypeptide of a leukocyte. Claim 25 is drawn to the composition of claim 1, wherein the ligand of the second amino acid sequence is a ligand for a cell surface polypeptide of an antigen presenting cell. Claim 26 is drawn to the composition of claim 25, wherein said ligand for a cell surface polypeptide is a ligand for a cell surface polypeptide of a professional antigen presenting cell. Claim 27 is drawn to the composition of claim 24, wherein said ligand for a cell surface polypeptide is a ligand for a cell surface polypeptide of a dendritic cell. Claim 28 is drawn to the composition of claim 1, wherein the ligand of the second amino acid sequence is a ligand for a mouse GM-CSF receptor. Claim 29 is drawn to the composition of claim 1, wherein the ligand of the second amino acid sequence comprises at least about five contiguous amino acids of a mouse GM-CSF. Claim 30 is drawn to the composition of claim 1, wherein the ligand of the second amino acid sequence comprises a mouse GM-CSF. Claim 32 is drawn to the composition of claim 1, wherein the ligand of the second amino acid sequence comprises at least five contiguous amino acids of a human GM-CSF. Claim 34 is drawn to the composition of claim 1, wherein the ligand of the second amino acid sequence is a ligand for a receptor

for an interleukin. Claim 35 is drawn to the composition of claim 1, wherein the ligand of the second amino acid sequence is a ligand for a receptor for a mouse interleukin. Claim 37 is drawn to the composition of claim 34, wherein said interleukin is chosen from a group comprising IL-2. Claim 38 is drawn to the composition of claim 34, wherein the ligand of the second amino acid sequence comprises at least about 5 contiguous amino acids of an interleukin. Claim 39 is drawn to the composition of claim 38, wherein said interleukin is chosen from a group comprising IL-2. Claim 40 is drawn to the composition of claim 34, wherein the ligand of the second amino acid sequence comprises an interleukin. Claim 41 is drawn to the composition of claim 40, wherein said interleukin is chosen from a group comprising IL-2. Claim 75 is drawn to the composition of claim 1, which comprises said fusion polypeptide bound to a carbohydrate on said antigen bearing target. Claim 76 is drawn to the composition of claim 1, which comprises said fusion polypeptide unbound to said antigen bearing target. Claim 77 is drawn to the composition of claim 1, wherein said antigen bearing target is a cell and said composition comprises said fusion polypeptide bound to a carbohydrate on the surface of a cell.

Hoo teaches a composition comprising an antigen bearing target and a fusion polypeptide comprising a first and second amino acid sequence (see claims 1-12, in particular) to be used in a vaccine for patients (see column 1, in particular). Hoo further teaches that the antigen bearing target includes a malignant melanoma tumor cell (see line 46 of column 9 and claim 6, in particular). The fusion polypeptide that Hoo teaches is exogenous to an antigen bearing target that is a cell, is expressed by said cell, and is

encoded by a nucleic acid comprised by said cell (see claim 1, in particular). As evidenced by Erbe et al (JCB, March 1993, 120(5):1227-1235), the first amino acid sequence of the fusion polypeptide of Hoo comprises a carbohydrate-binding domain of a naturally occurring lectin that would bind sialic acid (see columns 7-8 and P-selectin sequence of Table 2 in Hoo and page 1227 of Erbe et al, in particular). Hoo further teaches the second amino acid sequence as mouse GM-CSF or IL-2 (see lines 10-25 of column 3 and Example 1, in particular). Further, as evidenced by Cantrell et al (PNAS, September 1985, 82:6250-6254), mouse GM-CSF comprises at least five contiguous amino acids of human GM-CSF (see Figure 2 of Cantrell et al). It is noted that Il-2 is a ligand for an interleukin receptor (see column 6, in particular). The second amino acid sequences taught by Hoo are ligands for mammalian, mouse, cell surface polypeptides; also known as ligand for a cell surface polypeptide of a leukocyte, wherein the leukocyte is a dendritic cell, which is a professional antigen presenting cell (see columns 1-2, in particular). Hoo further teaches that the first amino acid sequence as N-terminal or C-terminal to the second amino acid sequence (see paragraph spanning columns 8-9, in particular). Hoo further teaches said fusion polypeptide unbound to said antigen bearing target and said fusion polypeptide bound to a carbohydrate on said antigen bearing target wherein said antigen bearing target is a cell and said composition comprises said fusion polypeptide that would be bound to a carbohydrate on the surface of said cell via the first amino acid sequence (see claims 1-12 and column 18, in particular).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 21, 23, 31, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoo (US Patent 5,891,432; 4/6/99) as applied to claims 1 and 21 above, and further in view of Cantrell et al (PNAS; September 1985, 82:6250-6254).

The teaching of claims 1 and 21 by Hoo is discussed above. Hoo does not specifically teach a composition wherein the second sequence comprises a ligand for a human cell surface polypeptide (see claim 23), wherein the ligand of the second amino acid sequence is a ligand for a human GM-CSF receptor (claim 31), or wherein the ligand of the second amino acid sequence comprises human GM-CSF (claim 33).

However, these deficiencies are made up in the teachings of Cantrell et al (PNAS, September 1985, 82:6250-6254).

Cantrell et al teaches human GM-CSF, a ligand for a human GM-CSF receptor (see Figure 2, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to make the composition taught by Hoo using the human GM-CSF ligand taught by Cantrell (see Figure 2, in particular) as the mammalian GM-CSF ligand of the second sequence because Hoo teaches the composition is to be used to treat patients (i.e. humans) (see column 1, in particular) and humans would be expected to respond to human GM-CSF. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for making the composition taught by Hoo using the human GM-CSF ligand taught by Cantrell (see Figure 2, in particular) as the mammalian GM-CSF ligand of the second sequence because Hoo teaches fusing mammalian GM-CSF to the first sequence (see Example 1, in particular) and Cantrell et al teaches human GM-CSF (see Figure 2, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Claims 1, 21, 23, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoo (US Patent 5,891,432; 4/6/99) as applied to claims 1 and 21 above, and further in view of Ishida et al (Nucleic Acids Research, 1985, 13(21):7579-7589).

The teaching of claims 1 and 21 by Hoo is described above. Hoo does not specifically teach a composition wherein the second sequence comprises a ligand for a human cell surface polypeptide (see claim 23) or a composition wherein the ligand of the second amino acid sequence is a ligand for a receptor for a human interleukin (see claim 36). However, these deficiencies are made up in the teachings of Ishida et al.

Ishida et al teaches human IL-2 (Figure 3, in particular), which is a ligand for a human cell surface polypeptide.

One of ordinary skill in the art at the time the invention was made would have been motivated to make the composition taught by Hoo using the human IL-2 ligand taught by Ishida et al (see Figure 3, in particular) as the mammalian IL-2 ligand of the second sequence because Hoo teaches the composition is to be used to treat patients (i.e. humans) (see column 1, in particular) and humans would be expected to respond to human IL-2. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for making the composition taught by Hoo using the human IL-2 ligand taught by Ishida et al (see Figure 3, in particular) as the mammalian IL-2 ligand of the second sequence because Hoo teaches fusing mammalian sequences (see Example 1, in particular) and Ishida et al teaches human IL-2 (see Figure 3, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Claims 1, 73, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoo (US Patent 5,891,432; 4/6/99) as applied to claim 1 above, and further in view of Natesan (US Patent 6,015,709; 1/18/00).

The teaching of claim 1 by Hoo is discussed above. Hoo does not specifically teach a composition wherein said fusion polypeptide further comprises a linker interposed between said first and second amino acid sequences (claim 73) or a composition wherein said linker has the formula $(Gly_xSer)_n$, wherein n is an integer between 1 and 10 (claim 74). However, these deficiencies are made up in the teachings of Natesan.

Natesan teaches linkers, including $(Gly_4Ser)_3$, that would be used to create fusion polypeptides (lines 40-64 of column 28, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to produce the composition taught by Hoo wherein the fusion polypeptide comprises a $(Gly_4Ser)_3$ linker as taught by Natesan (lines 40-64 of column 28, in particular) interposed between said first and second amino acid sequences because said linker would enhance flexibility of the fusion protein, reduce steric hindrance between any two fragments of the fusion protein, and facilitate the appropriate folding of the protein sequences (lines 40-64 of column 28, in particular). One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for producing the composition taught by Hoo wherein the fusion polypeptide comprises a $(Gly_4Ser)_3$ linker as taught by Natesan (lines 40-64 of column 28, in particular) interposed between said first and second amino acid

sequences because Natesan teaches methods of adding linkers between polypeptide sequences (lines 40-64 of column 28, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Claims 1, 10, and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoo (US Patent 5,891,432; 4/6/99) as applied to claim 1 above, and further in view of Parma et al (US Patent 5,780,228; 7/14/98) and in further view of Svehang et al (US Patent 6,406,698 B1; 6/18/02), Faulkner et al (International Immunology, June 2001, 13(6):713-721), or Hioe et al (Journal of Virology, December 1990, 64(12):6246-6251).

Teaching of claim 1 by Hoo is discussed above.

Hoo does not teach specific working examples wherein the heterologous membrane attachment domain (the first amino acid sequence) is described as including the amino acid sequences encompassed by instant claims 10 and 12-20. However, Hoo *does* suggest the use of any cell adhesion molecule as the heterologous membrane attachment domain (see columns 7-8 of Hoo, in particular).

Specifically, Hoo does teach a composition wherein said first amino acid sequence is taught to bind a sialic acid on a glycoprotein, said sialic acid comprising at least one of the following carbohydrate structures: N-acetylneuraminic acid, alpha-NeuNAc-(2->6)-Gal, alpha-NeuNAc-(2->6)-GalNAc, alpha-NeuNAc-(2->3)-Gal (claim 10), a composition wherein said first amino acid sequence comprises at least 10

contiguous amino acids of a hemagglutinin (see claim 12), a composition wherein said hemagglutinin is an influenza virus hemagglutinin (see claim 13), a composition wherein said contiguous amino acids of an influenza hemagglutinin are contiguous amino acids of an influenza hemagglutinin HA1 domain (see claim 14), the composition of claim 13 wherein said influenza virus is an influenza A virus (see claim 15), the composition of claim 15 wherein said influenza virus is of subtype that infects humans (see claim 16), the composition of claim 15, wherein said influenza virus is of an H1 subtype (see claim 17), the composition of claim 17, wherein said influenza virus is from strain A/PR/8/34 (see claim 18), the composition of claim 15, wherein said influenza virus is of an H2 or H3 subtype (see claim 19), or the composition of claim 13, wherein said influenza virus is of a subtype that does not infect humans (see claim 20). However, these deficiencies are made up in the teachings of Parma et al in view of Svehang et al, Faulkner et al, or Hioe et al.

As taught by Parma et al, at the time the invention was made the use of influenza hemagglutinin as a cell adhesion molecule was well-known, and well-characterized, in the art (see paragraphs bridging columns 1-2, in particular). Parma et al further teaches hemagglutinin binds sialic acid residues on cells (see lines 13-14 of column 2, in particular).

Svehang et al teaches at least 10 contiguous amino acids of a hemagglutinin comprising an HA1 domain, hemagglutinin derived from an influenza A virus, subtypes of hemagglutinin from viruses that infect humans such as subtype H1, hemagglutinin subtype H2, and hemagglutinin subtype H3 (see columns 2-4, in particular).

Hioe et al teaches H5 hemagglutinin, a subtype that does not infect humans (see page 6246, in particular).

Faulkner et al teaches influenza virus A/PR/8/34 (page 714, in particular), which comprises hemagglutinin.

One of ordinary skill in the art at the time the invention was made would have been motivated to use hemagglutinin from subtypes taught by Svehang et al, Hioe et al, and Faulkner et al as the first amino acid sequence in the composition taught by Hoo because Hoo teaches that said first amino acid sequence is to comprise a cell adhesion molecule (see columns 7-8 of Hoo, in particular) and Parma et al teaches the use of influenza hemagglutinin as a cell adhesion molecule was well-known, and well-characterized, in the art (see paragraphs bridging columns 1-2, in particular). One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for utilizing hemagglutinin from subtypes taught by Svehang et al, Hioe et al, and Faulkner et al as the first amino acid sequence in the composition taught by Hoo because Svehang et al, Hioe et al, and Faulkner et al teach the hemagglutinin subtypes that comprise adhesion molecules and Hoo teaches constructing a composition comprising a fusion polypeptide comprising an adhesion molecule (see claims 1-12 of Hoo, in particular). Further, as evidenced by Anders et al (Journal of Virology, November 1986, 476-482), hemmaglutinin molecules of Svehang et al, Hioe et al, and Faulkner et al can bind to a sialic acid on a glycoprotein, said sialic acid comprising at least one of the following carbohydrate structures: N-acetylneuraminic acid, alpha-NeuNAc-(2->6)-Gal, alpha-NeuNAc-(2->6)-GalNAc, alpha-

NeuNAc-(2->3)-Gal (see page 482, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Summary

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).